NYSTATIN - nystatin insert
Duramed Pharmaceuticals, Inc

DESCRIPTION
Nystatin is an antimycotic polyene antibiotic obtained from *Streptomyces noursei*.
Nystatin Vaginal Inserts, USP are available as oval-shaped compressed inserts for intravaginal administration, each containing 100,000 units Nystatin, USP. Inactive ingredients include corn starch, ethylcellulose, anhydrous lactose, microcrystalline cellulose, polyethylene glycol and stearic acid.

CLINICAL PHARMACOLOGY
Nystatin is both fungi-static and fungicidal *in vitro* against a wide variety of yeasts and yeast-like fungi. Nystatin acts by binding to sterols in the cell membrane of sensitive fungi with a resultant change in membrane permeability allowing leakage of intracellular components. Nystatin exhibits no appreciable activity against bacteria, protozoa, trichomonads or viruses.
Nystatin is not absorbed from intact skin or mucous membranes.

INDICATIONS AND USAGE
Nystatin Vaginal Inserts, USP are effective for the local treatment of vulvovaginal candidiasis (moniliasis). The diagnosis should be confirmed, prior to therapy, by KOH smears and/or cultures. Other pathogens commonly associated with vulvovaginitis (Trichomonas and Haemophilus vaginalis) do not respond to nystatin and should be ruled out by appropriate laboratory methods.

CONTRAINDICATIONS
This preparation is contraindicated in patients with a history of hypersensitivity to any of its components.

PRECAUTIONS

General
Discontinue treatment if sensitization or irritation is reported during use.

Information for Patients
The patient should be informed of symptoms of sensitization or irritation and told to report them promptly.
The patient should be warned against interruption or discontinuation of medication even during menstruation and even though symptomatic relief may occur within a few days.
The patient should be advised that adjunctive measures such as therapeutic douches are unnecessary and sometimes inadvisable, but cleansing douches may be used by nonpregnant women, if desired, for esthetic purposes.

Laboratory Tests
If there is a lack of response to Nystatin Vaginal Inserts, USP, appropriate microbiological studies should be repeated to confirm the diagnosis and rule out other pathogens before instituting another course of antimycotic therapy (see INDICATIONS AND USAGE).

Carcinogenesis, Mutagenesis, Impairment of Fertility
Long-term studies in animals have not been performed to evaluate carcinogenic potential, mutagenesis, or whether this medication affects fertility in females.

Pregnancy

Teratogenic effects: Pregnancy Category A
There have been no reports that use of Nystatin Vaginal Inserts by pregnant women increases the risk of fetal abnormalities or affects later growth, development and functional maturation of the child. Nevertheless, because the possibility of harm cannot be ruled out, Nystatin Vaginal Inserts should be used during pregnancy only if the physician considers it essential to the welfare of the patient.

Animal reproduction studies have not been conducted with Nystatin Vaginal Inserts.

Pediatric Use
Safety and effectiveness in pediatric patients have not been established.

ADVERSE REACTIONS
Nystatin is virtually nontoxic and nonsensitizing and is well tolerated by all age groups, even on prolonged administration. Rarely, irritation or sensitization may occur (see PRECAUTIONS).

DOSAGE AND ADMINISTRATION
The usual dosage is one insert (100,000 units nystatin) daily for two weeks.

The inserts should be deposited high in the vagina by means of the applicator. “Instructions for the Patient” are enclosed in each package.

HOW SUPPLIED

Nystatin Vaginal Inserts, USP:
Pale yellow mottled oval-shaped, flat face, beveled insert (Debossed ODYSSEY on one side and 705 on the other) are available in packages of 15 individually foil wrapped inserts, with applicator and “Instructions for the Patient”.
Store at 20° to 25°C (68° to 77°F) [See USP Controlled Room Temperature].

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